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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/083,307	05/22/98	LENTZ	M LEN101

QM12/0104

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3762	7

DATE MAILED: 01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/083,307	Lentz
Examiner	**Group Art Unit**
William Noggle	3762

☒ Responsive to communication(s) filed on *Sep 27, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-23* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-23* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 9/27/99 have been fully considered but they are not persuasive.

As to the argument that the one skilled in the art would not decrease the the cutoff size, the examiner respectfully disagrees. The applicant has stated that "there is no disclosure of the mechanism of action nor what was being removed by the filter, that was leading to cancer remission". On the contrary to the applicant's arguments, this would lead a person having ordinary skill in the art to narrow down the region in hopes to pinpoint the size of the active element or elements, and as stated before finding the optimum or workable range involves only routine skill in the art.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, a person skilled in the art would be inclined to utilize suspected treatments for cancer in a cocktail-type form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,8,9,16,18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713).

As to claims 1,2, and 9, Lentz (4,708,713) had disclosed a method and system for inducing an immune response against tumors comprising removing components in the blood having a molecular weight of 200,000 Daltons or less (page 2, lines 8-33). Lentz had also disclosed the system having inlet and outlet means for connection to a pump and tubing to recirculate the blood of a patient through the device (see figure 1). Lentz had not disclosed removing only components present in the blood having a molecular weight of 120,000 Daltons or less. However, Lentz (4,708,713), discloses the claimed invention except for the 120,000 versus the 200,000 Dalton cut off. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the upper range value from 200,000 to 120,000 Daltons, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to claims 3 and 4, the method of claim 1 is obvious in light of Lentz. Lentz had also disclosed the components being removed from one blood volume or in multiple treatments (page 7, lines 50-60).

As to claim 8, the method of claim 1 is obvious in light of Lentz. The use of vaccine against a transformed, infected, or diseased tissue was well known in the art at the time the invention was made, and the use of a vaccine would have been an obvious choice to a person skilled in the art, for example a medical doctor, at the time the invention was made.

As to claim 16, the system of claim 9 is obvious in light of Lentz. Radiation treatment was well known in the art at the time the invention was made. It was well known in the art at the time the invention was made to combine radiation treatment with another form of cancer treatment.

As to claims 18-20, the system of claim 9 is obvious in light of Lentz. The criticality of the type of filter used in the system was not specified by the applicant, therefore the filter type would be an obvious design choice to a person skilled in the art at the time the invention was made. Obvious design choices do not hold any patentable weight. Lentz had also disclosed the pore size of the filter medium as being between .02 and .05 microns and between .04 and .08 microns (page 10, claims 4 and 5).

As to claim 22, the system of claim 9 is obvious in light of Lentz. Lentz had also disclosed removing components from both the blood and plasma fractions (page 10, claims 4 and 5).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Chen et al. (Journal of Neuropathology and Experimental Neurology). The method of

claim 1 is obvious in light of Lentz. Lentz had not disclosed the method as removing soluble TNF 1 and 2 receptors from the blood. However, Chen et al. had disclosed the conclusion that TNF receptors help to evade the immune response against a tumor, page 549. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to remove TNF 1 and 2 by means of ultrafiltration, because these elements help to evade the immune response against tumors.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Okarma et al. (5,523,096). The system of claim 9 is obvious in light of Lentz. Lentz had not disclosed the device as having an absorption column for removing cytokines. However, Okarma et al. had disclosed an extracorporeal system for removing cytokines from the blood with an absorption matrix, see page 3, line 58 to page 4, line 14. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to combine Lentz's device with an absorption matrix to remove cytokines from the blood, because removal of cytokines can be used to control the immune system's response to septic shock or other diseases, see page 4, lines 3-5.

Claims 5,6,10-15,17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Wolpe (5,861,483).

As to claims 5,6,12,13,17, and 23, Lentz had disclosed a device for removing only components present in the blood having a molecular weight of 120,000 Daltons or less, see argument for claim 1. Lentz had also disclosed the use of an anticoagulant through the device, page 3, lines 66-

68. Lentz had not disclosed the device being in a kit and including an agent selected from the group consisting of anti-angiogenic compounds, procoagulant compounds, cytokines, chemotherapeutic agents, and radiation, in a dosage formulation. However, Wolpe had disclosed the need for stimulatory cytokines, specifically erythropoietin, to maintain a fully functional immune system, page 1, lines 25-45. The presumed mechanism which Lentz's invention is based on is removing immune inhibitors and letting the body's immune system combat the tumor. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to add a dose of erythropoietin to a kit including Lentz's device, because erythropoietin works to maintain a fully functional immune system, page 1, lines 25-45.

As to claims 10,11,14, and 15, Lentz and Wolpe had disclosed the claimed invention except for the use of chemotherapeutic agents, specifically alkylating agents, doxyrubicin, cardoplatinum, cisplatinum, and taxol, procoagulant compounds, or anti-angiogenic compounds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to simply replace erythropoietin with one of the above listed compounds or agents, since it has been held to be within the general skill of a worker in the art to select a known compound or agent on the basis of its suitability to the treatment of transformed, infected, or diseased tissue as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Noggle whose telephone number is (703) 308-4543.

RONALD STRIGHT
PRIMARY EXAMINER

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January 3, 2000